

File No. 4-01/2013-DC (Misc. 13 PSC Part II)
Govt. of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 06 JAN 2022

NOTICE

Subject: Evaluation of certain pre 1988 permitted Fixed Dose Combinations (FDCs) de novo for manufacture for sale in the country without due approval from Central Licensing Authority -regarding.

This is in continuation to this office notice dated 27.12.2021 whereby the meeting of the Expert Committee was postponed which was scheduled to be held on 29th & 30th December 2021.

Now, the expert committee again invites the concerned stakeholders for hearing through WebEx (Video Conference) on 27th & 28th January 2022 w.r.t. FDCs mentioned under Annexure A. Date and time of hearing is also mentioned under **Annexure A**.

It is requested that the concerned stakeholders may kindly make it convenient to give a presentation through WebEx (Video Conference) before the Expert Committee on these FDCs. In the event that the Stakeholders does not attend the hearing, the Committee reserves the right to make its decision on the basis of information available before it.

You are requested to kindly confirm your participation through e-mail at fdc@cdsco.nic.in by 24.01.2022 and also submit Power Point presentation (PPT) alongwith the presenter details, Mobile number, email ID, s. No. of FDC as per **Annexure-A**.

This is for information of all the concerned.



(Sanjeev Kumar)

Deputy Drugs Controller (India)

Copy to:

1. Dr. M.S. Bhatia, Prof. & Head, D/o Psychiatry, UCMS, New Delhi, Chairman, Expert Committee.
2. To all the experts committee members.
3. Indian Drug/Pharmaceuticals Association (IDMA/FOPE/CIPI/IPA/OPPI, etc.,) with the request to communicate it to your members and publicize it widely so that all concerned can avail this opportunity.
4. Website of CDSCO for information and necessary action by concerned stakeholders.

Annexure-A

S.No.	FDC Name	Date & Time of Hearing
1	Nimesulide +Paracetamol dispersible tablets	27.01.2022 11:30 AM to 06:00 PM
2	Paracetamol + Phenylephrine + Caffeine	
3	Amoxicillin + Bromhexine	
4	Pholcodine + Promethazine	
5	Imipramine + Diazepam	
6	Chlorpheniramine maleate+ Dextromethorphan+ Dextromethorphan + Guaifenesin + Ammonium chloride + Menthol	
7	Chlorpheniramine Maleate +Codeine syrup	
8	Ammonium Chloride + Bromhexine + Dextromethorphan	
9	Bromhexine +Dextromethorphan +Ammonium Chloride +Menthol	
10	Dextromethorphan +Chlorpheniramine + Guaifenesin +Ammonium Chloride	
11	Caffeine +Paracetamol +Phenylephrine + Chlorpheniramine	28.01.2022 11:30 AM to 06:00 PM
12	Paracetamol + Bromhexine +Phenylephrine +Chlorpheniramine + Guaifenesin	
13	Salbutamol + Bromhexine	
14	Chlorpheniramine +Codeine phosphate +Menthol syrup	
15	Phenytoin + Phenobarbitone sodium	
16	Paracetamol + Propyphenazone + Caffeine	
17	Ammonium Chloride + Sodium Citrate + Chlorpheniramine Maleate + Menthol	
18	Salbutamol + Hydroxyethyltheophylline (Etofylline) + Bromhexine	
19	Chlorpheniramine Maleate + Ammonium Chloride + Sodium Citrate	